

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document and the Version 1.2.0 Standard at <http://www.fda.gov/cber/guidelines.htm>.

Dated: May 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
Food and Drug Administration

[Docket No. 00D-1277]

**Draft Guidance for Industry: Fumonisin
Levels in Human Foods and Animal
Feeds; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds." The purpose of this draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

DATES: Submit written comments by August 7, 2000.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Draft Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds" to Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN) (address below), or Randall A. Lovell, Center for Veterinary Medicine (CVM) (address below). Send one self-addressed adhesive label to assist that office in processing your request. The draft guidance, CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," and CVM's "Background Paper in Support of Fumonisin Levels in Animal Feed," may also be accessed at the CFSAN or

CVM home page on the Internet at <http://www.cfsan.fda.gov> and <http://www.fda.gov/cvm>, respectively.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Henry Kim, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-0631, FAX 202-205-4422, or

Randall A. Lovell, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0176, FAX 301-827-1484.

SUPPLEMENTARY INFORMATION: FDA has developed a draft guidance document regarding the maximum recommended levels of fumonisins in corn used for production of human foods and animal feeds. Fumonisins are naturally occurring toxins produced by the molds *Fusarium moniliforme* (*F. verticillioides*), *F. proliferatum*, and other *Fusarium* species that are common contaminants of corn. Fumonisins have been linked to a variety of significant adverse health effects in livestock and experimental animals. Although human epidemiological studies are inconclusive at this time, based on a wide variety of significant adverse animal health effects, FDA believes that an association between fumonisins and human disease is possible.

The purpose of the draft guidance is to identify for the industry recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds. Based on information obtained from future national and international workshops on the risk from exposure to fumonisins, FDA will consider whether to establish tolerances, regulatory limits, or action levels, as appropriate, for fumonisins in

human foods and animal feeds, respectively, under 21 CFR Part 109—Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material and under 21 CFR Part 509—Unavoidable Contaminants in Animal Food and Food-Packaging Material.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The draft guidance document entitled "Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds" is being issued as a level 1 draft guidance consistent with GGP's. This draft guidance represents the agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Interested persons may submit written comments to the Dockets Management Branch (address above) on the draft guidance by August 7, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance, CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption," CVM's "Background Paper in Support of Fumonisin Levels in Animal Feed," and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
Health Care Financing Administration

[Document Identifier: HCFA-2540-96]

**Agency Information Collection
Activities: Proposed Collection;
Comment Request**

AGENCY: Health Care Financing Administration.